Remarks

Claims 21-50 and 55 are pending in the application.

Claim Rejections

35 USC § 112, Second Paragraph

Claim 55 has been rejected as allegedly indefinite.

Specifically, it is alleged that the term "relative abundance" is unclear. The specification describes at page 8, lines 1-15 that analytes such as FSH have different forms and that the relative proportions, i.e., the "relative abundance", of the forms are different in the menopausal state and the pre-menopausal state. The relative results from the one-step and two-step assays provide information about the relative abundance of the forms in a sample, which is indicative of the menopausal status. For instance, in the working example, for the relative abundance of the forms of FSH as detected by the taking result ratio of the two assays, the fertile woman has an assay result ratio of between 2.9 and 4.0, and the post-menopausal woman has an assay result ratio of between 1.2 and 1.8. Thus, the relative abundance of the forms, that is the relative proportions of the forms, as detected by the assay result ratio in the working example, indicates the menopausal status. Applicants urge that the term is clear.

Further, it is alleged that the phrase "wherein the specificity of at least one of the binding agents for the analyte compound is different for the two states of the analyte compound in the sample" is unclear. The phrase means that at least one, that is either one or both of the two binding agents, is more specific for one of the states than the other, as the Examiner has suggested. Accordingly, Applicants urge that the phrase is clear.

It is also alleged that "it is unclear how the amount of analytes in the first and second assays is related to the menopausal status of the female" in part (f) of claim 55, and that "there is no mention of the various states of the analyte nor their 'abundance' in determining the menopausal status." Applicants have amended claim 55 to clarify that the relative amount of analytes in the first and second assays are indicative of the relative abundance of the states of the analyte compound, which, as discussed above and as is recited in claim 55, are indicative of the menopausal status.

Finally, it is alleged that the recitation of "at least in part" is confusing. Applicants urge that the term "at least in part" is akin to the open-ended term "comprising," meaning that the method is open-ended and may include additional steps. Such terms mean that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.

Claims 23, 29 and 38 are rejected as indefinite because the recitation of "calculating a combined test result, expressed as a ratio of the amounts of ... complex formed in each of the assays" is allegedly confusing. Specifically, it is alleged that the recitation of "combined" implies some sort of total and it is therefore unclear how the total is expressed as a ratio. Applicants have amended to claims to clarify them.

Accordingly, Applicants respectfully request the withdrawal of the instant rejections for indefiniteness.

35 USC § 112, First Paragraph, Written Description

Claim 55 and its dependent claims have been rejected as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants urge that claim 55 is fully described in the specification as follows for each step of claim 55:

55. A method, comprising:

(a) providing a sample obtained from a human female, the sample comprising an analyte compound, the analyte compound being present in at least two different states, wherein a relative abundance of the two states of the analyte compound is related to the menopausal status of the female;

Support for this part of the claim is present, for example, on page 2, lines 9-17 and page 16, lines 1-10.

(b) providing a first and a second binding agent, wherein the specificity of at least one of the binding agents for the analyte compound is different for the two states of the analyte compound in the sample;

Support for this part of the claim is present, for example, on page 4, lines 21-27, page 9 and pages 12-15.

(c) *reacting a first portion of the sample with the first binding agent to form a first binding agent/analyte compound complex and subsequently reacting the first binding agent/analyte compound complex with the second binding agent to form a first binding agent/analyte compound/second binding agent complex;*

Support for this part of the claim is present, for example, on page 2, line 20 to page 5, line 16, page 10, lines 21-29 and page 15, line 30 through page 18.

Applicants note that the Examiner specifically alleges that the specification does not teach "the performance of a one-step and two-step assay on contemporaneous samples from the same source and determining the menopausal status of a female subject based at least in part on the amounts of the analyte in each of the assay."

Applicants draw to the Examiner's attention page 16, lines 1-4, which note that the method described in section 4 of the working example "was used to test 8 consecutive daily urine samples (around mid-cycle) *taken from one fertile woman*, and 9 consecutive daily urine samples *from one post-menopausal woman*. (emphasis added)" Section 4 describes the contemporaneous performance of the one-step and two-step assays on each sample taken from a single source, that is, either the fertile woman or the post-menopausal woman. The two assays were each performed on portions of the same sample taken from one of the women at a particular time point. The results of each assay performed on the portions of the same sample taken from one of the women were then expressed as a ratio. The fertile woman had a result ratio of between 2.9-4.0 for the various time points, and the post-menopausal woman had a result ratio of between 1.2 and 1.8 for the various time points. Thus, a difference in the range of result ratios was observed for the fertile woman versus the post-menopausal woman, and thus the result ratio is indicative of menopausal status.

(d) *reacting a second portion of the sample substantially simultaneously with the first binding agent and the second binding agent to form a first binding agent/analyte compound/second binding agent complex;*

As discussed above, support for this part of the claim is present, for example, on page 2, line 20 to page 5, line 16, page 10, lines 21-29 and page 15, line 30 through page 18.

(e) *determining the amount of first binding agent/analyte compound/second binding agent complex formed in each reacting step; and*

As discussed above, support for this part of the claim is present, for example, on page 2, line 20 to page 5, line 16, page 10, lines 21-29 and page 15, line 30 through page 18.

(f) *determining the menopausal status of the human female based at least in part on the amounts of first binding agent/analyte compound/second binding agent complex formed in each reacting step.*

As discussed above, support for this part of the claim is present, for example, on page 2, line 20 to page 5, line 16, page 10, lines 21-29 and page 15, line 30 through page 18.

Accordingly, Applicants respectfully request the withdrawal of the instant rejection for lack of written description.

Claim Rejections – 35 U.S.C. §103(a)

Claim 55 and its dependent claims 22-47 have been rejected under 35 U.S.C. §103(a) as allegedly obvious over Shah et al (U.S. 4,900,662) in view of Creus, et al. (Clinical Endocrinology. 1996 February. Vol. 44, No. 2, pp. 181-189).

Shah et al. do not teach or suggest using a pair of binding agents to detect an analyte pair in both a one-step and a two-step assay performed on portions of the same sample. Creus does not remedy this deficiency. Accordingly, the references when combined do not teach or suggest the claimed invention.

Applicants respectfully request the withdrawal of the rejection for obviousness over Shah et al (U.S. 4,900,662) in view of Creus, et al. (Clinical Endocrinology. 1996 February. Vol. 44, No. 2, pp. 181-189).

Double Patenting

Claim 55 and its dependent claims 22-50 have been provisionally rejected on the ground of nonstautory obviousness-type double patenting over claims 18-23, 26-28, 31-38 of copending application No. 10/780,904 in view of Shah et al (U.S. 4,900,662).

Claims 18-23, 26-28, 31-38 of copending application No. 10/780,904 do not teach or suggest using a pair of binding agents to detect an analyte pair in both a one-step and a two-step assay performed on portions of the same sample. As discussed above, Shah et al. do not

teach or suggest using a pair of binding agents to detect an analyte pair in both a one-step and a two-step assay performed on portions of the same sample. Thus, Shah et al. does not remedy the deficiencies of claims 18-23, 26-28, 31-38 of copending application No. 10/780,904.

Applicants respectfully request the withdrawal of the provisional rejection for obviousness-type double patenting over claims 18-23, 26-28, 31-38 of copending application No. 10/780,904 in view of Shah et al (U.S. 4,900,662).

Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted,
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Date: October 3, 2006